K042989

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BIOMET

APR 2 8 2005

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: Rx90™ Low Profile Acetabular System

Common Name: Acetabular component of a total hip replacement

Classification Name(s):
1) Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3358)
2) Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3350)
3) Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353)
4) Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR 888.3310)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: The Rx90™ Low Profile Acetabular System is substantially equivalent to Biomet products cleared through the following 510(k) submissions:

K920639	Rx90™ Acetabular Component System
K926107	ArCom® Acetabular Liners and Components
K030055	Expanded indications for Non-Cemented Porous Coated Total Hip Prostheses
K023357	ArCom® Polyethylene Liners and Components (1050 Resin)

Device Description: The Rx90™ Low Profile Acetabular System is a metal backed shell with a polyethylene liner intended for cemented or cementless replacement of the acetabular portion of a total hip replacement. The metallic shell is available in diameters of 40mm to 70mm and two different hole configurations. Liners are available with internal diameters of 22mm, 28mm, 32mm and 36mm. Liner styles include Hi-Wall, 10 Degree, MROM, +5mm Hi-Wall 180° Hi-Wall, Flat Face and Constrained.

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Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

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574.267.8137 ■ E-MAIL
biomet@biomet.com

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Intended Use: The Rx90™ Low Profile Acetabular System is indicated for cemented or non-cemented use in cases of:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
5) Revision of previously failed total joint replacement.

Specific indications for compatible components that can be used with the above acetabular shells include:

Salvage/Oncology Hip and Total Femur System (K002757, K021380, K033871)

1. Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis, traumatic arthritis
2. Correction of varus, valgus or post traumatic deformity
3. Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement
4. Ligament deficiencies
5. Tumor resections
6. Treatment of non-unions, femoral neck and trochanteric fracture of the proximal femur with head involvement, unmanageable using other techniques
7. Revision of previously failed total joint replacement
8. Trauma

Interlocking hip stems are indicated for non-cemented application in cases of revision, trauma, fracture, oncology or other situations where severe proximal bone loss may compromise the fixation and stability of a standard type hip replacement prosthesis. (K990830, K042774)

The Freedom™ Constrained Liners are intended for general use in skeletally mature individuals undergoing primary and/or secondary revision surgery at high risk of hip dislocation due to a history of prior dislocation, joint or bone loss, soft laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered. (K030047)

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Summary of Technologies: The technological characteristics (materials, design, sizing and indications) of the Rx90™ Low Profile Acetabular System are similar to or identical to the predicate devices.

Non-Clinical Testing: Mechanical testing has demonstrated the ability of the device to perform as expected.

Clinical Testing: None provided

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 8 2005

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K042989
Trade/Device Name: Rx90™ Low Profile Acetabular System
Regulation Number: 21 CFR 888.3358, 888.3353, 888.3350, 888.3310
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis; Hip joint metal/ceramic/polymer semi-constrained cemented or non-porous uncemented prosthesis; Hip joint metal/polymer semi-constrained cemented prosthesis; Hip joint metal/polymer constrained cemented or uncemented prosthesis
Regulatory Class: II
Product Code: LPH, LZO, JDI, KWZ, MEH
Dated: January 26, 2005
Received: January 28, 2005

Dear Ms. Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

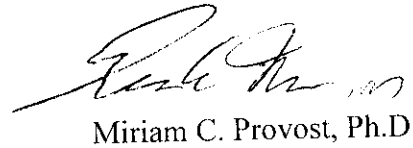
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042989

Device Name: Rx90™ Low Profile Acetabular System

Indications For Use:

Rx90™ Low Profile Acetabular Shells are intended for cemented or non-cemented total hip replacement in cases of

1. Non-Inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis
3. Correction of functional deformity
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed total hip arthroplasty.

Specific indications for compatible components that can be used with the above acetabular shells include:

Salvage/Oncology Hip and Total Femur System (K002757, K021380, K033871)

9. Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis, traumatic arthritis
10. Correction of varus, valgus or post traumatic deformity
11. Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement
12. Ligament deficiencies
13. Tumor resections
14. Treatment of non-unions, femoral neck and trochanteric fracture of the proximal femur with head involvement, unmanageable using other techniques
15. Revision of previously failed total joint replacement
16. Trauma

Interlocking hip stems are indicated for non-cemented application in cases of revision, trauma, fracture, oncology or other situations where severe proximal bone loss may compromise the fixation and stability of a standard type hip replacement prosthesis. (K990830, K042774)

The Freedom™ Constrained Liners are intended for general use in skeletally mature individuals undergoing primary and/or secondary revision surgery at high risk of hip dislocation due to a history of prior dislocation, joint or bone loss, soft laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered. (K030047)

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Restorative

K042989